**CLINICAL TRIAL REQUEST INTAKE FORM**

|  |
| --- |
| **Instructions** |
| This form facilitates the assessment of the appropriateness of funding drugs in a clinical trial through the publicly funded health care system, as well as funding the costs of drug administration/delivery. The request will be reviewed jointly by the Systemic Treatment Quality Based Program (ST-QBP) and the New Drug Funding Program (NDFP), where appropriate.  Prior to completing the form, please ensure that the request is for a **new clinical trial**, and:   * Meets CCO’s definition of a systemic treatment clinical trial: **is an intervention to evaluate a systemic anti-cancer drug or biologic which has undergone institutional (peer) review and has obtained (or in the process of obtaining) ethics approval at the institutional or provincial level.** * Has not previously been reviewed and listed on the webpage; refer to the **CCO clinical trials assessment table** which can be found on the [Systemic Treatment Clinical Trials webpage](http://www.cancercare.on.ca/toolbox/ClinicalTrials/) .   Complete **Sections A and B** of this form and **Section C** if appropriate and submit to [clinicaltrials@cancercare.on.ca](mailto:clinicaltrials@cancercare.on.ca).   * **Sections A** and **B** are **required** sections and must be completed. * **Section C** is applicable if there is a possibility that the patient will be treated with one or more NDFP, EBP, EAP, and/or LU drug(s) within the trial or subsequent to the trial. * For more information, please refer to the [Draft Policy 2.0](https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=351979), [FAQ’s](https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=351977), and funding eligibility criteria. * New Drug Funding Program (NDFP) drugs and indications:   <https://www.cancercare.on.ca/toolbox/drugs/ndfp/>   * Evidence Building Program (EBP) drugs and indications:   http://www.cancercare.on.ca/toolbox/drugs/ebprogram/   * Exceptional Access Program (EAP) drugs and indications: <http://www.health.gov.on.ca/en/pro/programs/drugs/pdf/frequently_requested_drugs.pdf> * Limited Use (LU) drugs and indications: <https://www.healthinfo.moh.gov.on.ca/formulary/index.jsp> |
| **SECTION A: REQUESTOR INFORMATION** |
| **Date:** Click here to enter a date. |
| **Provincial Applicant Name & Title**: Click here to enter text. |
| **E-mail**: Click here to enter text.  **Phone Number**: Click here to enter text. |
| **Submitting Treatment Centre**: Choose an item.  **If Other, Please Specify:** Click here to enter text.  *Note: CCO only requires one submission for each clinical trial from a provincial clinical trials investigator.* |

|  |
| --- |
| **SECTION B: CLINICAL TRIAL INFORMATION** |
| **Clinical Trial Title**: Click here to enter text. |
| **Clinical Trial Abbreviation:** Click here to enter text.  *Examples: KAITLIN, AURA, CATHERINE* |
| **NCT Number:** Click here to enter text.  *Note: if there is no NCT number associated with the trial, please indicate another ID (e.g. OCT, EudraCT, etc.)* |
| **Web Link to Trial (if available)**: Click here to enter text.  *Example: Clinicaltrials.gov* |
| **Treatment Intent:** Choose an item. |
| **Disease Site:** Choose an item.  *If disease site is not listed or multiple disease sites are applicable, please specify: Click here to enter text.* |
| **Trial Sponsor:** Click here to enter text. |
| **Funding Source(s):** Click here to enter text.  *Examples: Industry, Cooperative Group (NCIC, OCOG, other), local investigator initiated trial* |
| **Anticipted Start Date (Month/Year):** Click here to enter text. |
| **Please identify the standard of care the patient would receive if not on the clinical trial (options include: supportive care, a specific treatment regimen, etc.):** Click here to enter text. |

**Section C** To be completed if the clinical trial involves one or more drugs that are currently publicly funded through NDFP, EBP, EAP, and/or LU, or if there is a possibility that the patient will be treated subsequently with one or more drugs from one of the above funding sources. If neither of these conditions apply, there is no need to fill out Section C and the form with completed Sections A and B can be submitted to [clinicaltrials@cancercare.on.ca](mailto:clinicaltrials@cancercare.on.ca).

|  |
| --- |
| **SECTION C: NDFP/EAP/LU DRUG REQUEST INFORMATION** |
| **Clinical Trial Schema – please provide the schema of the trial (copy and pasted version from the protocol are accepted)** |
| **Will patients on the clinical trial be treated with an NDFP, EAP, or LU drug?**    *If yes, please complete the table below. Please use one table per drug. If there is more that one drug please click on the drug name box below and click*  *on the bottom right hand side to insert a new table.* |

|  |  |
| --- | --- |
|  | |
| **Drug name** | Click here to enter text. |
| **Is the drug funded by the sponsor?** | Choose an item. |
| **What is the indication for the drug in the trial?** | Click here to enter text. |
| **What is the dose and frequency of administration in the trial?** | Click here to enter text. |
| **Is the drug being used in accordance with NDFP/EBP/EAP/LU criteria?** | Choose an item. |

|  |  |
| --- | --- |
| **Please provide a description of the anticipated patient management in the following circumstances:** | |
| **The patient is withdrawn from study due to excessive toxicity** | Click here to enter text. |
| **There is disease progression** | Click here to enter text. |
| **The patient refuses further participation on the trial** | Click here to enter text. |
| **There is disease recurrence after the trial is completed** | Click here to enter text. |

|  |  |
| --- | --- |
| **Please answer the following questions with regard to investigational new drugs:** | |
| **What is the mechanism of action of the experimental drug?** | Click here to enter text. |
| **Would cross resistance be anticipated if the most appropriate next treatment included an NDFP/EBP/EAP/LU drug?** | Click here to enter text. |

|  |
| --- |
| **Is there a possibility that the patient will be treated with an NDFP, EAP, or LU drug subsequent to the completion of the trial? (disease recurrence,disease progression, trial drug discontinuance for toxicity)**    *If yes, please complete the table below. Please use one table per drug. If there is more that one drug, please click on the drug name box below and click*  *on the bottom right hand side to insert a new table.* |

|  |  |
| --- | --- |
|  | |
| **Drug name** | Click here to enter text. |
| **Is the drug funded by the sponsor?** | Choose an item. |
| **What is the indication for the drug in the trial?** | Click here to enter text. |
| **What is the dose and frequency of administration in the trial?** | Click here to enter text. |
| **Is the drug being used in accordance with NDFP/EBP/EAP/LU criteria?** | Choose an item. |

|  |
| --- |
| **SECTION D: FOR CCO USE ONLY** |
| **Date Received:** Click here to enter a date. |